

§ 878.4660 Skin marker.

(a) *Identification.* A skin marker is a pen-like device intended to be used to write on the patient's skin, e.g., to outline surgical incision sites or mark anatomical sites for accurate blood pressure measurement.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§ 878.4680 Nonpowered, single patient, portable suction apparatus.

(a) *Identification.* A nonpowered, single patient, portable suction apparatus is a device that consists of a manually operated plastic, disposable evacuation system intended to provide a vacuum for suction drainage of surgical wounds.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

[53 FR 23872, June 24, 1988, as amended at 65 FR 2318, Jan. 14, 2000]

§ 878.4700 Surgical microscope and accessories.

(a) *Identification.* A surgical microscope and accessories is an AC-powered device intended for use during surgery to provide a magnified view of the surgical field.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

[55 FR 48440, Nov. 20, 1990, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§ 878.4730 Surgical skin degreaser or adhesive tape solvent.

(a) *Identification.* A surgical skin degreaser or an adhesive tape solvent is a device that consists of a liquid such as 1,1,2-trichloro-1,2,2-trifluoroethane; 1,1,1-trichloroethane; and 1,1,1-trichloroethane with mineral spirits in-

tended to be used to dissolve surface skin oil or adhesive tape.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§ 878.4750 Implantable staple.

(a) *Identification.* An implantable staple is a staple-like device intended to connect internal tissues to aid healing. It is not absorbable.

(b) *Classification.* Class II.

§ 878.4760 Removable skin staple.

(a) *Identification.* A removable skin staple is a staple-like device intended to connect external tissues temporarily to aid healing. It is not absorbable.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

[53 FR 23872, June 24, 1988, as amended at 65 FR 2318, Jan. 14, 2000]

§ 878.4780 Powered suction pump.

(a) *Identification.* A powered suction pump is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter.

(b) *Classification.* Class II.

§ 878.4800 Manual surgical instrument for general use.

(a) *Identification.* A manual surgical instrument for general use is a nonpowered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin